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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,400	05/07/2001	Ai J. Lin	P66823US0(WRAIR-01)	9445

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04/09/2003

Office of the Staff Judge Advocate
U.S. Army Medical Research and Materiel Command
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Fort Detrick, MD 21702-5012

EXAMINER

PATEL, SUDHAKER B

ART UNIT PAPER NUMBER

1624

DATE MAILED: 04/09/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/849,400

Applicant(s)
Ai J. Lin et al

Examiner
SUDHAKER PATEL, D.Sc. Tech.

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 22, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-50 is/are pending in the application.
- 4a) Of the above, claim(s) 34-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32, 33, 49, and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 18
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 17 6) ☐ Other:

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DETAILED ACTION

Applicants' communication paper # 16 dated 1/22/03 is acknowledged.

Applicants' presentation of new claims 32-50 after canceling original claims 1-32 has been reviewed by the Examiner. Applicants' arguments and remarks have been considered, but not found persuasive for allowance of this application as a single patent for the various reasons stated bellow.

I. Claim 32 recites a single compound.

II. Claim 33 which is dependent of claim 32 recites a broader meaning than claim 32 upon which it is dependent by introducing "prodrug" and "pharmaceutically acceptable salt". These terms are not included in claim 32 and constitute a broader meaning than claim 32 under 35 U.S.C. 112 paragraph 4. (See MPEP 608.01 (I)).

III. Claim 34 which is dependent on claim 33 recites complex composition involving unknown supplementary active compounds. The scope of the claim is not same as claim 33.

IV. Claim 35 lacks antecedent basis. See MPEP 2173.05(e)

V. Claim 35 also introduces new subject matter by way of structural formula wherein the molecule is based not on tricyclic (= fused 3 benzene rings) but on monocyclic rings having a bridging atoms N which connects 2 phenyl ring and the side chain $-(CH_2)_n-Y$.

VI. Claims 40-44 are related to antimalarial chemosensitizing agent which is different than claims 49-50.

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VII. Claims 45-48 are related to modulating resistance to an antimalarial in a cell or organism which is different than claims 49-50.

These claims which are related to cell and organism will fall in class 435 for the examination purpose which will be dealt by another Art Unit. Examiner's Art Unit is 1624 which deals with Nitrogenous heterocyclic compounds.

VII. Various rejections of Office communication paper # 15 dated 10/22/02:

Rejections withdrawn:

(A). Rejections made under 35 U.S.C. 112 para one: Applicants cancellation of claims and remarks are sufficient for withdrawal of the same. Accordingly, the rejections are withdrawn.

(B). Rejections made under 35 U.S.C. 102(a) and 35 U.S.C. 103(a): Applicants cancellation of claims, and remarks are sufficient for withdrawal of these rejections. Accordingly, these rejections are now withdrawn.

Rejections maintained: Rejections made under 35 U.S.C. 112 para. Second are maintained further for claims 32-50 for the reasons already stated in earlier Office Action paper # 15 dated 10/22/02.

VIII. Examiner's position:

For the reasons stated above, Examiner has decided to issue new Restriction/election as follows:

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IX.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims(in part) 32,33,49,50, drawn to a compound of claim 32, wherein original Formula of canceled claim 1 has : $X = S$ i.e. tricyclic phenothiazine core, together with the species wherein $Y = \text{pyrrolidinyl}$ with integer $n = 4$, its simple composition(s) not involving supplementary active compounds, and a method of treating malaria (in human), classified in class 544, subclasses 14,35,41,44, class 548 subclasses 566, 579.
 - II. Claims (in part) 32,33,49,50, , drawn to compounds not included in invention of Group I , classified in class e.g. class 546 (wherein $X = \text{Carbon}$), classes 564,585(wherein X and tricyclic structure is absent altogether and Y could be open or forming a closed ring with $N(R_1R_2)$ and, subclasses various depending on the nature of Y , R_1 , and R_2 .
 - III. Claims(in part) 34-44, drawn to complex binary compositions and a method of antimalarial chemosensitizing activity(in human),classified in class-514, subclasses various depending on the nature of the make up of the components of the complex binary mixtures. If this invention is elected further restriction/election will be required. Additionally, a single species by way of working example must be disclosed with all variables exactly defined .

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- IV. Claims(in part) 34-39,45-48, drawn to compositions and method of modulating resistance to antimalarial activity in a cell or organism, classified in class 435, subclass various depending on variables.
2. The inventions are distinct, each from the other because of the following reasons:
Inventions I-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Veramapil and compounds having phenothiazine core can also be used for the utility as recited herein (See Ford J.M., et al "Pharmacology Of Drugs That alter Multidrug Resistance in Cancer",The American Soc. For Pharm. And Exptl.. Therap. Vol;. 42, pages 155-199(1990)).
3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-IV, restriction for examination purposes as indicated is proper.
4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
5. This application contains claims directed to the following patentably distinct species of the claimed invention: Compound of Claim 32, Various compounds of claim 35 wherein X is other

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than S, X is absent(diphenyl amine structure), Y is either open not forming fusion with N of Y = - NR1R2 forming a saturated ring other than pyrrolidine.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 32, 33,34,36,37,38,39, and claims 40-48 involving complex composition and their specific use are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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6. A telephone call was made to Ms.S.K. Sundby on 4/7/03 to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). See interview summary enclosed with this action.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

X.

Information Disclosure Statement

The Information Disclosure Statement submitted as paper # 17 dated 1/22/03 is considered by the Examiner and a signed copy of PTO Form 1449 is enclosed with this communication for applicants' record.

XI.

Conclusion

Allowable Subject Matter

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Claims 32, 33, 49,50 related to a compound, its simple composition without complex binary supplementary active compounds, and a specific method of treating malaria to human would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

The closest prior art reference of record(U.S.P. 5741791) discloses the compounds having phenothiazine, phenoxazine, propyl 3-piperidine- or 3-pyrrolidin- carboxylic acid hydrochlorides and their use for reducing blood glucose.

The reference does not suggest or indicate to arrive at the instant compound having unsubstituted phenothioazin 4-butyl pyrrolidine and the utility as anti-malarial.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel, D.Sc.Tech. whose telephone number is (703) 308 4709.


The examiner can normally be reached on Monday thru' Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah can be reached at (703) 308 4716 or Sr. Examiner Mr. Richard Raymond at 703 308 4523.

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A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.


SP/April 7, 2003.


RICHARD L. RAYMOND
PRIMARY EXAMINER
ART UNIT 1624